

peri-urethrally into tissue at at least one injection site a composition comprising an effective amount of relatively soft, malleable, elastic, biologically compatible prosthetic micro particles dispersed in a non-retentive compatible physiological vehicle comprising polyvinyl pyrrolidone, the micro particles of the composition further being of a designed average particle size distribution and characterized by a rough surface having a plurality of surface irregularities generally randomly formed therein, such that the effects of average particle size and average particle surface roughness cooperate in combination in an autogenous manner to essentially prevent loss of the micro particles from any injection site, the particles remaining to be incorporated as long-term tissue augmentation.

*E' Cmt*  
<sup>2</sup>  
54. A method as defined in claim <sup>1</sup>~~53~~ wherein the micro particles possess an average unidimensional particle size in the range of from about 100 microns to about 600 microns.

<sup>3</sup>  
55. A method as defined in claim <sup>3</sup>~~53~~ wherein the micro particles comprise a polysiloxane.

<sup>4</sup>  
56. A method as defined in claim <sup>2</sup>~~54~~ wherein the micro particles comprise a polysiloxane.

<sup>5</sup>  
57. A method as defined in claim <sup>2</sup>~~54~~ wherein the micro particles are polydimethylsiloxane.

<sup>6</sup>  
58. A method for long-term treatment of incontinence comprising the steps of making a plurality of spaced injections into the submucosal layer of the urethra of a composition

E' Cont  
comprising an amount of relatively soft, malleable, elastic, biologically compatible prosthetic micro particles dispersed in a non-retentive compatible physiological vehicle comprising polyvinyl pyrrolidone, the micro particles of the composition further being of a designed average unidimensional particle size distribution between <sup>B</sup>30 and <sup>B</sup>3000 microns, and characterized by a rough surface having a plurality of surface irregularities generally randomly formed therein, characterized by indentations, cavities and pores forming openings upon the surface of the particles, with the dimensions of the indentations, cavities and pores being generally in a range between <sup>B</sup>10 angstroms and <sup>B</sup>500 microns, such that the effects of average particle size and average particle surface roughness cooperate in combination in an autogenous manner to essentially prevent loss of the micro particles from any injection site, the particles remaining to be incorporated as long-term tissue augmentation.

<sup>7</sup>59. A method as defined in claim <sup>6</sup>58 wherein the micro particles possess an average unidimensional particle size in the range of from about 100 microns to about 600 microns.

<sup>8</sup>60. A method is defined in claim <sup>B</sup>58<sup>4</sup> wherein the micro particles comprise a polysiloxane material.

<sup>9</sup>61. A method as defined in claim <sup>7</sup>59 wherein the micro particles comprise a polysiloxane.

<sup>10</sup>62. A method for long-term treatment of gastric reflux comprising the steps of making a plurality of injections at spaced

sites into the appropriate submucosal space selected from the esophageal-gastric junction and gastric-pyloric junction a composition comprising an amount of relatively soft, malleable, elastic, biologically compatible micro particles dispersed in a non-retentive compatible physiological vehicle comprising polyvinyl pyrrolidone, the micro particles of the composition further being of a designed average unidimensional particle size distribution between <sup>B</sup>30 and <sup>B</sup>3000 microns, and characterized by a rough surface having a plurality of surface irregularities generally randomly formed therein, characterized by indentations, cavities and pores forming openings upon the surface of the particles, with the dimensions of the indentations, cavities and pores being generally in a range between <sup>B</sup>10 angstroms and <sup>B</sup>500 microns, such that the effects of average particle size and average particle surface roughness cooperate in combination in an autogenous manner to essentially prevent loss of the micro particles from any injection site, the particles remaining to be incorporated as long-term tissue augmentation.

*E,  
Cont*  
<sup>11</sup>63. A method as defined in claim <sup>10</sup>62 wherein the micro particles possess an average unidimensional particle size in the range of from about 100 microns to about <sup>B</sup>600 microns.

<sup>12</sup>64. A method is defined in claim <sup>10</sup>62 wherein the micro particles comprise a polysiloxane material.

<sup>13</sup>65. A method is defined in claim <sup>11</sup>63 wherein the micro particles comprise a polysiloxane material.

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*E*  
*Cm't*  
~~66~~. A method for long-term treatment of urological and gastric disorders comprising the step of injecting submucosally or peri-urethrally into tissue at at least one injection site a composition comprising an effective amount of relatively soft, malleable, elastic, biologically compatible prosthetic micro particles, characterized by a rough surface having a plurality of irregularities generally randomly formed therein, and dispersed in a non-retentive, non-retained compatible physiological vehicle, wherein the vehicle is eliminated from the injection site and the micro particles being an average particle size distribution and surface roughness such that the effects of average particle size and average particle surface roughness cooperate in combination in an autogenous manner to essentially prevent loss of the micro particles from any injection site, the particles remaining to be incorporated as long-term tissue augmentation.

~~67~~. A method as defined in claim ~~66~~<sup>14</sup> wherein the surface irregularities of the micro particles describe indentations, cavities and pores forming a very irregular surface including openings within the particles, the micro particles having an average unidimensional particle size generally between 30 and 3000 microns with the dimensions of the indentations, cavities and pores within the particles being generally in a range between 10 angstroms and 500 microns.

~~68~~. The method of claim ~~67~~<sup>15</sup> wherein the vehicle comprises polyvinyl pyrrolidone.